IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

DR. JOSEPH CICCIO, et al.,)	
)	
Plaintiffs,)	
)	Civil No. 3:19-cv-00845
v.)	Jury Demand
)	•
SMILEDIRECTCLUB, LLC, et al.,)	Judge Trauger
)	Magistrate Judge Brown
Defendants.)	6

PROTECTIVE ORDER

This matter is before the court on Plaintiffs' Motion for Entry of Protective Order. By Order dated December 26, 2019, the Motion was GRANTED in part and DENIED in part. For good cause shown, discovery in the above-captioned litigation ("Proceeding") SHALL be governed by the following Protective Order. The Parties shall serve a copy of this Protective Order simultaneously with any discovery request made to a third party. The terms of this Protective Order are as follows:

- **Applicability**. This Protective Order is applicable to all plaintiffs and defendants, any additional parties joined in this Proceeding (collectively, the "Parties"), and any third-parties required to respond to discovery in this Proceeding, for the sole purpose of facilitating discovery in the Proceeding and protecting the confidentiality and other interests of the Parties and thirdparties throughout the course of this Proceeding. This Order authorizes the disclosure of information protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), including all applicable regulations and guidance issued by the Secretary of the United States Department of Health and Human Services (collectively, the "HIPAA Rules"), including specifically 42 C.F.R. Part 2 and 45 C.F.R. §§ 164.512(e)(1)(ii)(B), 164.512(e)(1)(v), as well as all state laws and regulations regarding the privacy and security of personal information (collectively with the HIPAA Rules, the "Privacy and Security Rules"). This Order constitutes a Qualified Protective Order, as that term is defined in the Privacy and Security Rules. The parties are expressly prohibited from using or disclosing information protected by the Privacy and Security Rules obtained pursuant to this Order for any purpose other than this Proceeding.
- 2. **Scope of Use**. All "Confidential," "Confidential—Attorneys' Eyes Only," and "Confidential—Outside Counsel Only" information produced or exchanged in the course of this Proceeding shall be used solely for the purpose of prosecuting or defending this Proceeding, including mediation, trial preparation, trial, and appeal, and for no other purpose whatsoever and shall not be disclosed to any person except in accordance with the terms of this Protective Order.

- 3. **Designation of Information**. Any document, data, testimony, interrogatory answer, response to a request to admit, exhibit, and other information produced, served or otherwise disclosed to or by any Party or third party during the Proceeding as "Confidential," "Confidential—Attorneys' Eyes Only," or "Confidential—Outside Counsel Only" (collectively "Confidential Material") shall be treated in the manner that is consistent with the definitions and procedures set forth in this Protective Order. Any party or third-party designating information as Confidential Material shall make a good faith determination of the designation chosen among the below 3.a-3.c prior to producing such information. Documents previously produced shall be retroactively designated by notice in writing by Bates number or such other means that will allow for the identification of such documents. The unintentional failure by a Party or third party to designate specific documents or materials as containing Confidential Material shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. Upon notice to each Party of such failure to designate, each Party shall cooperate to restore the confidentiality of the inadvertently disclosed information.
 - a. "Confidential" Designation. A Party or third party may designate as "Confidential" any Confidential Material that it reasonably and in good faith believes contains any trade secret, other personal information of any Party or third party, or other confidential research, development, or commercial information, as referenced in Fed. R. Civ. P. 26(c)(1)(G), provided that the Confidential Material has been subject to efforts to maintain confidentiality that are reasonable under the circumstances.
 - b. "Confidential—Attorneys' Eyes Only" Designation. A Party or third party may designate as "Confidential—Attorneys' Eyes Only" any Confidential Material that it reasonably and in good faith believes is of such a commercially or competitively sensitive nature that disclosure to persons other than those listed in paragraph 11 could reasonably be expected to result in injury.
 - c. "Confidential—Outside Counsel Only" Designation. A Party or third party may designate as "Confidential—Outside Counsel Only" any Confidential Material that it reasonably and in good faith believes is of such a commercially or competitively sensitive nature that disclosure to persons other than those listed in paragraph 12 could reasonably be expected to result in injury.
- 4. **Confidential Health Information**. The Parties desire to ensure the privacy of patient/customer medical records, patient/customer claims information, and other information that the Parties have determined might contain sensitive personal health information ("Confidential Health Information"). Confidential Health Information is intended to encompass any patient health information protected by any state or federal law, including, but not limited to, "Protected Health Information," as defined below, and agree that any Confidential Health Information shall be deemed "Confidential" and any such information concerning a third party shall be deemed "Confidential—Attorneys' Eyes Only" and, as such, subject to the terms of this Protective Order.
 - a. **Protected Health Information**. Protected Health Information, as used herein, has the same scope and definition as set forth in 45 C.F.R. §160.103.

Without limiting the generality of the foregoing, Protected Health Information includes, but is not limited to, health information, including demographic information, relating to: the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, which identifies or reasonably could be expected to identify the individual. It also includes, but is not limited to, medical bills, claims forms, charges sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanation of benefits, checks, notices, and requests, and includes all notes, summaries, compilations, extracts, abstracts or oral communications that are based on or derived from Protected Health Information, regardless of form or format. Protected Health Information also includes information that contains the following identifiers of a patient/customer or of a relative, employer, or household member of a patient/customer:

- i. names;
- ii. all geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code;
- iii. all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, age, and date of death;
 - iv. telephone numbers;
 - v. fax numbers;
 - vi. electronic mail addresses;
 - vii. social security numbers;
 - viii. medical record numbers;
 - ix. health plan beneficiary numbers;
 - x. account numbers;
 - xi. certificate/license numbers;
- xii. vehicle identifiers and serial numbers, including license plate numbers;
 - xiii. device identifiers and serial numbers:
 - xiv. web universal resource locators ("URLs");
 - xv. internet protocol ("IP") address numbers;
 - xvi. biometric identifiers, including finger and voice prints;
 - xvii. full face photographic images and any comparable images;
- xviii. any other unique identifying number, characteristic, or code;

and

xix. any other information that the producing party knows could be used alone or in combination with other information to identify an individual who is subject of the information.

Confidential Health Information does not include any document or information in which the producing party has redacted the identifiers listed above and does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information. A producing party may, but is not required to, perform such redactions before producing documents

that originally contained Confidential Health Information so long as the redactions do not result in prejudice to another Party.

b. **Safeguards for Confidential Health Information**. The Parties also seek to ensure that any person who receives and stores Confidential Health Information in connection with this Proceeding will develop, implement, maintain, and use appropriate administrative, technical, and physical safeguards to preserve the privacy, integrity, and confidentiality of any Confidential Health Information, and to prevent unpermitted use or disclosure of any Confidential Health Information they may receive from any person in connection with this Proceeding. At a minimum, all Parties and persons or entities who might receive Confidential Health Information (including all signatories to Appendix A of this Order) agree that they will (1) comply with the Privacy and Security Rules; (2) establish contractual controls that require any vendors, experts, or third parties that might receive Confidential Health Information to comply with the Privacy and Security Rules; and (3) undertake due diligence to verify that the privacy and security protections of any such vendors, experts, or third parties comply with the Privacy and Security Rules. Confidential Health Information will be securely destroyed, deleted, or returned pursuant to the provisions of paragraph 15 below.

5. **Document Production and Exhibits.**

- a. **Documents**. Documents containing Confidential Material, and any copies thereof, shall be designated as such by including a legend of "Confidential," "Confidential—Attorneys' Eyes Only," or "Confidential—Outside Counsel Only" on each page as to which confidentiality is claimed. Said legend shall be made so as not to obscure any of the Confidential Material's content.
- b. **ESI**. With respect to any Confidential Material that is produced as electronically stored information ("ESI") and that is not susceptible to the imprinting of a stamp signifying its confidential nature, the producing party may label the production media "Confidential," "Confidential--Attorneys' Eyes Only," or "Confidential--Outside Counsel Only" and/or alter the file name of the native ESI to include "Conf." or "Atty.Only" or "OutsideCounsel" and shall inform all recipients in writing of the designation at the time that Confidential Material is produced; otherwise, the ESI shall be marked with the legend as provided in paragraph 5(a) above. Whenever any ESI is reduced to a hard-copy document, such copy shall be marked with the legend as provided in paragraph 5(a) above.
- 6. **Depositions**. A deposition or portion thereof may be designated as "Confidential," "Confidential—Attorneys' Eyes Only," or "Confidential—Outside Counsel Only" by making that designation on the record during the deposition or by denominating by page and

¹ "Secure destruction" means: "Securely overwriting or wiping data using a secure file deletion utility to ensure that the information cannot be recovered. For those devices that cannot be overwritten (e.g., defective hard drives, CDs/DVDs), the device must be destroyed prior to disposal."

line those portions of the deposition which are to be considered "Confidential," "Confidential-Attorneys' Eyes Only," or "Confidential-Outside Counsel Only" within fortyfive (45) days of receiving the transcript and exhibits and so informing all Parties of the designation. Until the forty-five-day period has passed, the deposition transcript shall be treated as "Confidential—Attorneys' Eyes Only." If testimony is orally designated as "Confidential," "Confidential-Attorneys' Eyes Only," or "Confidential-Outside Counsel Only" during the course of a deposition, the court reporter shall transcribe the pages so designated in a separate volume marked "CONFIDENTIAL" or "CONFIDENTIAL-ATTORNEYS' EYES ONLY" or "CONFIDENTIAL—OUTSIDE COUNSEL ONLY." Any portion of a deposition so designated, or separately bound, shall not be filed with the court, except in accordance with paragraph 8 of this Protective Order. Notwithstanding the above, when notified to do so, persons attending depositions, other than the witness and his or her outside counsel provided that the witness and his or her outside counsel have signed Appendix A to this Protective Order, must leave the room before any discussion of any Confidential Material, or any excerpts, summaries, or information derived therefrom, that the person is not entitled to review under this Protective Order.

- 7. **Documents Produced by Third-Parties**. With respect to any document or ESI or other material that is produced or disclosed by any third party without a designation of "Confidential," "Confidential—Attorneys' Eyes Only," or "Confidential—Outside Counsel Only," any Party may designate such material as Confidential Material within thirty (30) days of actual knowledge of the production or disclosure of the material, or such other time as may be agreed upon by the Parties.
 - a. Parties may designate such material by sending written notice of a designation to all other Parties in possession or custody of such previously undesignated material. The designating Party shall either provide the Bates number(s) of the material in the written notice or provide a copy of the designated material bearing the appropriate legend. Within thirty (30) days of receipt of such notice, or such other time as may be agreed upon by the Parties, any Parties receiving such notice or copy of the designated material pursuant to this subparagraph shall return to the designating Party all undesignated copies of such material in their custody or possession, shall inform the designating Party that all undesignated copies of such material in their custody or possession have been discarded, or shall affix the legend to all copies of such designated material in their custody or possession.
 - b. Upon notice of designation pursuant to this paragraph, the Parties also shall: (i) make no further disclosure of such designated material or information contained therein, except as allowed under this Order; (ii) take reasonable steps to notify any persons who were provided copies of such designated material of the terms of this Order; and (iii) take reasonable steps to reclaim any such designated material in the possession of any person not permitted access to such information under the terms of this Order.
 - c. No Party shall be deemed to have violated this Order for the sole reason that such material has been disclosed or used in a manner inconsistent with the subsequent designation, prior to notification of the subsequent designation.

- 8. **Documents Generated During Suit**. All pleadings, motions, memoranda, briefs, deposition transcripts, discovery requests and responses, exhibits, and other documents that produce, quote, paraphrase, summarize, or otherwise contain information from Confidential Material, if filed with the court, shall either be filed in redacted form or, if the court so allows for the particular document at issue, filed under seal pursuant to Local Rule 5.03. As set out in Local Rule 5.03, documents containing Confidential Material will not be automatically sealed upon filing or if used at trial; rather, sealing will be allowed only upon the filing of a motion for leave to file under seal which demonstrates compelling reasons to seal the documents and that the sealing is narrowly tailored to those reasons. Consistent with Local Rule 5.03, if the Party intending to use the information from Confidential Material files a motion for leave to file under seal, and the court denies the motion, the Party will be considered to have complied with the terms of this paragraph and may file the information from Confidential Material publicly.
- 9. **Restrictions on Use of Confidential Material**. Except as agreed by the designating party or its counsel or as otherwise provided herein, Confidential Material, and any excerpts, summaries, or information derived therefrom:
 - a. shall be maintained in confidence;
 - b. may be disclosed only to persons entitled to access thereto under the terms of this Protective Order;
 - c. shall be used by such persons to whom it is disclosed only for the purposes of prosecuting or defending this Proceeding, including appeals, and for no other purpose;
 - d. may be photocopied or otherwise reproduced only as reasonably necessary for this Proceeding; and
 - e. will be securely destroyed or returned at the conclusion of this Proceeding pursuant to the provisions of paragraph 15 below.

Nothing herein shall prevent disclosure beyond the terms of this Protective Order if the Party or third party designating the information as Confidential Material consents in writing to such disclosure of its designated material. Further, nothing herein shall prevent disclosures as may be required by and pursuant to federal or state regulations, including but not limited to those promulgated and enforced by the Securities and Exchange Commission. If a party determines that it has a regulatory obligation to disclose any Confidential Material—as so designated by another party or by a third party (the "producing party")—the party that intends to disclose the information shall provide notice of its intent to the producing party at least five (5) business days before making a disclosure.

10. **Authorized Users of "Confidential" Material**. Except as agreed in writing by the designating party or as otherwise provided herein, information designated "Confidential" subject to this Protective Order, or extracts, summaries, or information derived therefrom, shall not be disclosed or shown to any person except the following:

- a. In-house counsel for any Party engaged in the litigation of this Proceeding and the employees and personnel who work with such attorneys to whom it is necessary that the material be shown for purposes of this Proceeding.
- b. Outside counsel for any Party engaged in the litigation of this Proceeding and the employees and personnel who work with such attorneys to whom it is necessary that the material be shown for purposes of this Proceeding.
- c. Any individual Party, as well as employees or former employees of a corporate Party engaged in assisting that Party's attorneys in the conduct of this Proceeding, or a member of a putative Class who is a client of and actively engaged in assisting Plaintiffs' counsel, to the extent reasonably necessary to enable the attorneys for that Party or client to render professional services in the Proceeding. Confidential Material will not be disclosed to a former employee until that person has signed and delivered to counsel for the Party that is the former employer a statement in the form attached hereto as Appendix A. Confidential Material will not be disclosed to an individual member of a putative Class or an individual representative of any corporate entity that is a member of a putative Class until that person has signed and delivered to counsel for the Plaintiffs a statement in the form attached hereto as Appendix A. Counsel for the Parties shall exchange all such signed statements on a Confidential—Outside Counsel Only basis five (5) business days before the individual is provided Confidential Information.
- d. An expert or consultant retained or employed to advise or assist counsel in prosecuting or defending the Proceeding, after such expert or consultant has signed and delivered to counsel for the Party who is providing the Confidential Material to the expert or consultant a statement in the form attached hereto as Appendix A.
- e. A Party's outside service-providers and consultants regarding document and ESI processing, hosting, review, and production, which includes any e-Discovery consultants and trial consultants provided such persons have signed and delivered to counsel for the Party retaining the outside service-provider or consultant a statement in the form attached hereto as Appendix A.
- f. A deponent who is the author, bona fide recipient, or is reasonably expected to possess knowledge relating to the information discussed in the document, but only in connection with the preparation for or during the course of a noticed deposition in this Proceeding, and provided that the deponent has signed a statement in the form attached hereto as Appendix A.
- g. A court reporter and videographer in connection with the course of a deposition in this Proceeding, provided that such persons have signed a statement in the form attached hereto as Appendix A.

- h. The court, other court officials (including court reporters), and the trier of fact.
- Authorized Users of "Confidential—Attorneys' Eyes Only" Material. Except as agreed in writing by the designating party or as otherwise provided herein, no information that is designated "Confidential—Attorneys' Eyes Only" pursuant to this Protective Order, or extracts or summaries therefrom, shall be disclosed or shown to any person except those persons listed in paragraphs 10(a), (b), (d), (e), (f), (g) and (h).
- 12. **Authorized Users of "Confidential—Outside Counsel Only" Material.** Except as agreed in writing by the designating party or as otherwise provided herein, no information that is designated "Confidential—Outside Counsel Only" pursuant to this Protective Order, or extracts or summaries therefrom, shall be disclosed or shown to any person except those persons listed in paragraphs 10(b), (d), (e), (f), (g) and (h).
- 13. **Challenging Designation**. If any Party reasonably and in good faith believes that information designated as Confidential Material under this Protective Order is not properly subject to the confidentiality designation assigned to it, or should not be subject to this Protective Order, that Party shall notify the designating Party or third party in writing and provide a description of the Confidential Material and a concise statement of the basis for the challenge, and serve copies of such notice to counsel for all other Parties. Counsel shall confer in good faith in an effort to resolve any dispute concerning such designation. If the objection cannot be resolved by agreement within seven (7) days from the date of service of the written objection, any Party may move the court for a determination as to whether the designation is appropriate. The burden of establishing the appropriate level of confidentiality shall be on the Party making the designation. The protection of the Confidential Material afforded by the Protective Order shall continue as originally designated until the court issues an order on the motion. The use of the designation Outside Counsel Eyes Only should be used with great care. The Parties are on notice the Court reserves the right to impose costs including attorney's fees for any finding the use of such designation has been improperly used.
- 14. **Modification of Order**. This Order may be modified or amended either by written agreement of the Parties submitted to the court for approval or by order of the court upon good cause shown.
- 15. **Conclusion of Proceeding**. The provisions of this Protective Order shall continue in effect with respect to any Confidential Material until expressly released by the Party or third party designating the Confidential Material, and if applicable, such effectiveness shall survive the final determination of this Proceeding. Within sixty (60) days (unless the parties agree to a longer period) of the final determination of this Proceeding, including any appeal, all Confidential Material, including all hard and electronic copies, derivations, and summaries thereof, shall be either (a) returned to the disclosing Party or third party; or (b) securely destroyed or deleted, with a written certification of such secure destruction or deletion provided to the disclosing Party or third party. Counsel of record are permitted to retain a copy of attorney work product, which may incorporate information from Confidential Material, provided that (1) all such retained attorney work product, and counsel's further retention or further use thereof,

shall remain subject to the terms of this Order, and (2) counsel's retention of such attorney work product is in compliance with the Privacy and Security Rules. For purposes of this Protective Order, the "final determination of this Proceeding" shall be deemed to be the latter of (i) full settlement of all claims; (ii) final judgment herein after the completion and exhaustion of all appeals, re-hearings, remands, trials and reviews, if any, of this Proceeding; or (iii) the expiration of all time limits under federal law for the filing of or application for all appeals, re-hearings, remands, trials or reviews of this Proceeding, including the time limits for the filing of any motions or applications for extension of time pursuant to applicable law.

DONE and ORDERED this 9th day of December 2019.

/S/ Joe B. Brown Joe B. Brown United States Magistrate Judge

APPENDIX A

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

DR. JOSEPH CICCIO, et al.,)	
)	
Plaintiffs,)	
)	Civil No. 3:19-cv-00845
V.)	Jury Demand
)	
SMILEDIRECTCLUB, LLC, et al.,)	Judge Trauger
)	Magistrate Judge Brown
Defendants.)	

AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

- 1. I am familiar with and agree to be bound by the terms of the Protective Order in the above-captioned litigation ("Proceeding"). I understand that my execution of this Agreement to Be Bound by Protective Order indicates my agreement to be bound by the Protective Order and is a prerequisite to my access or review of any information or documents designated as Confidential Material pursuant to the Protective Order. I further understand that my execution of this Agreement indicates that I am a person who is allowed to access or review information or documents designated as Confidential Material pursuant to the Protective Order.
- 2. I will access and review Confidential Material that may be provided to me solely for the purpose of my role in assisting with prosecuting or defending this Proceeding, or testifying in this Proceeding, and for no other purpose whatsoever. I further agree that I will not disclose any Confidential Material to any person except as allowed by the terms of the Protective Order.
- 3. I will only make such copies of or notes concerning Confidential Material as are necessary to enable me to render the assistance or testimony required in connection with this Proceeding. Upon the final determination of this Proceeding, I shall promptly and securely destroy or delete all Confidential Material provided to me as well as any notes or derivations thereof. I understand that my obligation to honor the confidentiality of such material will continue even after this Proceeding concludes.
- 4. I understand that all Confidential Health Information, as defined in the Protective Order, is subject to state and federal statutory and regulatory privacy and security standards, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act of 2009 (the "HITECH Act"), and regulations adopted thereunder by the U.S. Department of Health and Human Services, 45 C.F.R. Parts 160, 162, and 164 (the "HIPAA Rules"). All Confidential Material disclosed by any Party or third party to this Proceeding that contains Confidential

Health Information shall be treated in accordance with those standards, as applicable. Capitalized terms used, but not otherwise defined in this agreement, shall have the same meanings as those terms in HIPAA Rules.

- 5. By executing this Agreement to Be Bound by Protective Order, I agree that I will not use or disclose any Confidential Health Information in a manner that would violate the HIPAA Rules and will only use or disclose any Confidential Health Information for the purpose of this Proceeding or to comply with judicial process or any applicable statute or regulation. I also agree that I will develop, implement, maintain, and use appropriate administrative, technical and physical safeguards to preserve the privacy, integrity, and confidentiality of any Confidential Health Information, and to prevent unpermitted use or disclosure of any Confidential Health Information I receive from any person in connection with this Proceeding.
- 6. I understand that failure to comply with the terms of the Protective Order may be punishable by contempt of court and may result in civil liability to any party or person damaged thereby. I consent to the jurisdiction of the United States District Court for the Middle District of Tennessee (without any time limit) for the purpose of enforcing the Protective Order.

DATED this day of	, 20
(Signature)	
(Printed Name)	